

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

CARDINAL HEALTH, INC.,

Petitioner,

v.

NATIONAL BOARD OF MEDICAL  
EXAMINERS,

Respondent.

Civil Action No. 2:20-mc-00057-BMS

**DECLARATION OF KEN RIDGLEY IN SUPPORT OF NBME’S OPPOSITION TO  
MOTION TO COMPEL PRODUCTION OF DOCUMENTS BY NON-PARTY NBME  
AND NBME’S CROSS-MOTION TO QUASH RULE 30(B)(6) SUBPOENA**

I, Ken Ridgley, declare under penalty of perjury under the laws of the United States that the foregoing is true and correct:

1. My name is Ken Ridgley. I am more than twenty-one years of age. I have personal knowledge of the facts stated below based upon my own work for the National Board of Medical Examiners (“NBME”) or, where indicated, based on information provided to me by individuals within the company who have provided me information within their areas of responsibility, and I am competent to testify regarding the same.

2. I am employed by the NBME as Vice President, Test Development, and have been since February 2019. NBME is a nonprofit organization located in Philadelphia. NBME has no connection to Cardinal Health, Inc., and has nothing to do with the underlying opioid litigation.

3. NBME develops and administers the United States Medical Licensing Examination (“USMLE”), a standardized test designed to assess a medical school student’s or medical school graduate’s ability to apply the concepts, knowledge, and principles necessary to provide effective

and safe patient care. The USMLE is designed to evaluate broad-based medical knowledge and skills to ensure aspiring doctors have the minimum competency to practice medicine. The exam does not establish the general standard of care for physicians, much less for those whose practices focus on pain management. An examinee's performance on the USMLE, either generally or on questions specifically relating to pain management or prescribing medications, would not reflect whether that individual later met the applicable standard of care. As far as I am aware, no court has ever relied on the USMLE as reflecting the relevant standard of care for pain management or any other aspect of the delivery of healthcare.

4. Jurisdictions across the nation rely on USMLE as part of their physician licensure process, requiring prospective doctors to pass all components of the exam before they may practice medicine unsupervised.

5. The USMLE is comprised of three distinct "Steps," taken at various points over the course of an individual's graduate medical education: Step 1, Step 2 (which includes Step 2 Clinical Knowledge ("CK") and Step 2 Clinical Skills ("CS")), and Step 3. With the exception of Step 2 CS, which evaluates communication and clinical skills using interactions with role-playing "standardized" patients, each USMLE exam primarily consists of multiple-choice questions. Step 2 CK, for example, is a nine-hour exam comprised of approximately 315 multiple-choice questions.

6. USMLE questions address a wide range of medical conditions and content areas, none of which relate specifically to "pain management." The USMLE includes questions on General Principles of Foundational Science; the Immune System; Blood & the Lymphoreticular System; the Behavioral Health Nervous System & Special Senses; Skin & Subcutaneous Tissue; the Musculoskeletal System; the Cardiovascular System; the Respiratory System; the

Gastrointestinal System; the Renal & Urinary System; Pregnancy, Childbirth, & the Puerperium; the Female Reproductive System & Breast; the Male Reproductive System; the Endocrine System; Multisystem Processes & Disorders; Biostatistics, Epidemiology/Population Health, & Interpretation of the Medical Literature; and the Social Sciences.

7. Developing USMLE questions is time-consuming and expensive. The process requires input from subject matter experts across the country, numerous meetings, as well as support from NBME editors and other technical staff. It costs at least \$500,000 to create a single multiple-choice USMLE exam form, and approximately \$3,000 to develop a single question and set of potential answers. On average, it takes two years to develop each multiple-choice question on the Step 1, Step 2 CK or Step 3 USMLE exams, from inception to its first administration as a scored item on the USMLE.

8. The USMLE is a “secure” test, which means that the questions are kept confidential before and after an exam is administered. Strict security measures are in place in NBME’s offices that limit who can access USMLE questions. In addition, to help ensure that USMLE questions are kept confidential, NBME registers USMLE questions with the United States Copyright Office under its special regulations for “secure tests.” Pursuant to these regulations, one or more NBME employees travel to Washington, D.C. to participate in an item-by-item review of USMLE questions by a Copyright Office examiner, with the questions displayed on an NBME laptop computer. NBME also holds examinees to strict confidentiality obligations, prohibiting them from reproducing or disseminating any information relating to exam questions or answers before or after testing. NBME has sanctioned examinees who did not respect the confidentiality of exam content. I have been informed that it has also pursued litigation involving the unauthorized disclosure of USMLE test questions and answers.

9. NBME goes to great lengths to maintain the confidentiality of its USMLE questions because, like most standardized tests, NBME reuses questions from prior exams to “equate” scores (that is, to adjust for variation in the difficulty of test forms so that the reported scaled scores reflect the same level of performance test-to-test).

10. Beyond its “live,” reusable USMLE questions, NBME also has questions that have been retired, questions that were tested on the USMLE but will not be used on future USMLEs, and questions that have been made public as samples for prospective examinees. While some of these questions might be used on other assessments that NBME develops and thus still warrant designation as confidential (such as subject matter exams that are used by medical schools), they are not intended to be used on future USMLE exam forms.

11. When live USMLE questions are disclosed without authorization, it jeopardizes the validity of future exam results. The risk is that questions will be answered correctly not because a given examinee has mastered the applicable content but because of prior access to the questions and answers. That harms not only other test-takers and NBME (which, as noted, invests substantial time and money into developing high-quality questions), but also the licensing boards and general public that rely on USMLE scores to help ensure that only those with the skill and knowledge to practice medicine unsupervised are licensed as doctors.

12. It is my understanding that secure test questions that will be used on future USMLE exam forms have never been produced by NBME to any third parties in the context of a lawsuit.

13. Because of the ongoing public health crisis and stay-at-home order, NBME’s offices in Philadelphia are closed, with no date currently set for reopening.

14. The USMLE Step 1, Step 2 CK, and Step 3 exams are administered in computer-based testing centers operated a third-party vendor, Prometric. Testing occurs not just in the

United States but in locations around the world. Other testing programs also administer tests in Prometric testing centers.

15. Given social-distancing requirements, NBME has been confronting substantial operational challenges relative to administering the USMLE. Prometric testing centers have been closed entirely or in substantial part for at least the past two months, disrupting normal testing operations.

16. NBME has had to devote significant man-hours to exploring ways to administer its multiple-choice and clinical-skills exams in the context of a worldwide pandemic. Many staff, diverted from their typical duties, are dedicating their time to creating new test forms so students can test at medical schools, while working to account for special groups of test-takers, such as international medical students and disabled examinees who need accommodations, and attending to their normal job responsibilities.

17. It is my understanding that NBME has been asked to produce all test questions from the past 24+ years “relating to pain management.” To do that, NBME would first need to identify which questions “relate” to “pain management.” These terms are vague, particularly in the context of a broad medical licensing exam like the USMLE, where questions routinely involve conditions that might cause pain or a patient who is experiencing pain. Many USMLE questions refer to pain but have nothing to do with what I assume is meant by “pain management,” and even a smaller fraction involves addressing pain.

18. Putting aside how one should define “pain management” as it has been used by Cardinal Health, NBME would need to search its question bank of tens of thousands of “live,” reusable questions for those that include the term “pain.” Based on an on-site review of sample USMLE exams by a panel of external experts in 2014, the number of such questions could be

around 25 percent, if that representation held for the entire pool of live USMLE questions. And because only a relatively small percentage of questions that mention “pain” actually relates specifically to treating or “managing” pain, NBME staff members would need to read through and evaluate every question that mentions “pain” to see if it is responsive to the production request.

19. This would be a time-consuming and burdensome process in the best of circumstances. It would be significantly more difficult amidst the global health pandemic. NBME employees are working remotely and cannot access content in the usual fashion. The process of doing word-searches and retrieving questions that are stored electronically is much slower and more cumbersome working remotely.

20. I understand that NBME has been asked to produce USMLE questions from 1996 forward. I have been told by our staff that these questions are not all in an electronic format. Exams from 1996 through 1999 apparently exist only (or at least primarily) in paper copy, if they exist at all in our records, and therefore cannot be electronically searched for specific terms. Identifying responsive questions from those years would require tracking down those paper-based exams, assuming that is possible, and reviewing each and every unique exam form, question-by-question, to identify items that reference pain. Someone would then need to make a judgment call as to which of those questions relate to “pain management.”

21. The process of identifying responsive USMLE questions would be extremely labor intensive and expensive. It would likely require at least three NBME staff members (one for each Step exam) and at least one technical expert. Moreover, given current work demands, staff assigned to this project would likely need to work nights and on weekends. I estimate that it would take these three staff members up to twelve weeks to identify and retrieve responsive

questions that are in an electronic format, and much longer to identify such questions from exams that exist only in a paper format.

22. Such lost staff hours of course have a cost for NBME. If one assumes 12 weeks of lost staff time for three staff members, the cost of producing documents requested by Cardinal Health would likely exceed \$75,000 without counting the attorneys' fees and expenses that we have incurred already and would incur.

23. Assuming I could identify appropriate staff to perform the work that would be required to identify and retrieve for production all USMLE questions from 1996 forward "relating to pain management," and that those staff need to perform that work in addition to their normal job responsibilities, the production project would likely take several months to conclude in the current environment and would distract from NBME's efforts to administer its licensing exam.

24. I have reviewed the deposition topics that Cardinal Health has identified in the deposition subpoena that it served on NBME. Given the breadth of those topics, it is unlikely that any one employee could reliably speak on NBME's behalf on every referenced topic, even if the questioning related only to the past year or some other narrower time period. It is my understanding, however, that the questioning would relate to the past 24+ years. It is my further understanding that the deposition subpoena asks NBME to produce someone to testify not only about what NBME did or knew at various times over that 24+ year period, but also what other individuals or entities knew or did in that time period, who were somehow affiliated with NBME. The requested testimony would be virtually impossible to provide, other than with any answers along the lines of "I do not know," or "This might not be accurate, but....", or "It is my understanding that....., but...."

25. If NBME had to produce one or more witnesses in response to Cardinal Health's deposition subpoena, there is a good chance that I would be designated to testify on at least some of the topics referenced in the subpoena. It would take me many hours to do the necessary background investigation and research to address those topics in even a cursory fashion. Those hours, the other hours needed to prepare to be deposed, and the hours spent being deposed, would of course come at the expense of my other work responsibilities.

26. By way of illustration, my work responsibilities over the past two months currently include the following: I lead the operational development of assessments for USMLE and other healthcare specialty exams. I am also leading an initiative to increase USMLE testing at regional testing centers. I have been working, on average, 10-12 hours each day for the past two months and have frequently worked nights and weekends.

27. In my opinion, my ability to perform my responsibilities as the person in charge of test development for the USMLE program would be meaningfully interrupted and compromised if I must appear for deposition in response to the deposition subpoena from Cardinal Health. If other NBME employees also had to prepare for and appear at such a deposition, I believe that their work would be negatively impacted in a similar manner.

28. The information provided in this declaration has been assembled on very short notice, while our offices are closed, and staff are working remotely. Where estimates of time or expense have been provided, I believe those estimates to be accurate but also note that significantly more time and effort would be required to confirm the estimates.

29. Because I am working remotely due to the pandemic and do not have a printer, I have not been able to personally sign this Declaration. My electronic signature is provided below



instead. If requested by either Cardinal Health or the Court, I will find a way to provide a version of this Declaration containing my handwritten signature.

I declare under penalty of perjury that the foregoing is true and correct.

Executed/authorized on May 29, 2020

/s/ Ken Ridgley  
Ken Ridgley